

Notice of Allowability

Application No.

09/830,954

Examiner

Christopher J Nichols, Ph.D.

Applicant(s)

SOLOMON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12 November 2004.
2. ☒ The allowed claim(s) is/are 122,124,126,127,131,132,134 and 136-147.
3. ☒ The drawings filed on 12 November 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>1.11.05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 12 November 2004 has been received and entered in full.
2. The Terminal Disclaimer filed 14 January 2005 has been received, entered, and approved.

Withdrawn Objections And/Or Rejections

3. The Objection to the Specification as set forth in the previous Office Action (12 May 2004) is hereby *withdrawn* in view of Applicant's amendments (12 November 2004).
4. All rejections of the claims as set forth at in the previous Office Action (12 May 2004) are *withdrawn* in view of Applicant's amendments (12 November 2004).

Election/Restrictions

5. Claims **122-131** are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 132-147, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 132-147 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.
6. Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on 11 September 2003 is hereby *withdrawn*.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

8. In the Title:

BACTERIOPHAGE DISPLAYING ABETA EPITOPES AND METHOD OF USE

9. In the claims:

Claims 1-121 (Cancelled)

Claim 122 (Currently Amended) A pharmaceutical composition in unit dosage form, comprising a pharmaceutically acceptable carrier, and, as an active ingredient, a ~~virus~~ bacteriophage ~~that is an *in vivo* non-propagatable particle~~ displaying a polypeptide, wherein said polypeptide comprises at least one epitope of beta-amyloid (A β), and wherein said at least one epitope elicits A β -binding antibodies against said epitope when administered to a subject, and wherein said antibodies inhibit aggregation of said beta-amyloid.

Claim 123 (Cancelled)

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Claim 124 (Currently Amended) The pharmaceutical composition of claim 122, wherein said ~~virus~~ bacteriophage is selected from the group consisting of a double stranded DNA virus, a single stranded DNA virus, a positive strand RNA virus and a negative strand RNA virus.

Claim 125 (Cancelled)

Claim 126 (Currently Amended) The pharmaceutical composition of claim ~~125~~ 122, wherein said bacteriophage is capable of propagation in bacterial flora in said ~~recipient~~ subject.

Claim 127 (Currently Amended) The pharmaceutical composition of claim ~~125~~ 122, wherein said bacteriophage is capable of propagation in Escherichia coli.

Claims 128-130 (Cancelled)

Claim 131 (Currently Amended) The pharmaceutical composition of claim 122, wherein said ~~virus~~ bacteriophage is selected such that less than 30 days following an introduction of a triple dose of 10^{10} units thereof to the ~~recipient~~ subject, a titer of said antibodies is above 1:50,000, as is determined by ELISA.

Claim 132 (Previously Presented) A method of treating Alzheimer's disease, comprising introducing a pharmaceutical composition in accordance with claim 122 into a body of a

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recipient in need thereof so as to inhibit aggregation of beta-amyloid and treat Alzheimer's disease.

Claim 133 (Cancelled)

Claim 134 (Currently Amended) The method of claim 132, wherein said ~~virus~~ bacteriophage is selected from the group consisting of a double stranded DNA virus, a single stranded DNA virus, a positive strand RNA virus and a negative strand RNA virus.

Claim 135 (Cancelled)

Claim 136 (Currently Amended) The method of claim ~~135~~ 132, wherein said bacteriophage is capable of propagation in bacterial flora in said recipient.

Claim 137 (Currently Amended) The method of claim ~~135~~ 132, wherein said bacteriophage is capable of propagation in Escherichia coli.

Claim 138 (Previously Presented) The method of claim 132, wherein the Alzheimer's disease is early onset Alzheimer's disease.

Claim 139 (Previously Presented) The method of claim 132, wherein the Alzheimer's disease is late onset Alzheimer's disease.

Claim 140 (Previously Presented) The method of claim 132, wherein the Alzheimer's disease is presymptomatic Alzheimer's disease.

Claim 141 (Currently Amended) The method of claim 132, wherein said ~~virus~~ bacteriophage is introduced into the body of the recipient so as to inhibit aggregation of beta-amyloid by applying said ~~virus~~ bacteriophage to an olfactory system of the recipient.

Claim 142 (Currently Amended) A pharmaceutical composition in accordance with claim 122, wherein said polypeptide is A β .

Claim 143 (Currently Amended) A pharmaceutical composition in accordance with claim 122, wherein said epitope is EFRH (SEQ ID NO: 1), DAEFRH (residues 1-6 of SEQ ID NO: 3), DAEFRHD (residues 1-7 of SEQ ID NO: 3), or DAEFRHDSG (residues 1-9 of SEQ ID NO: 3).

Claim 144 (Currently Amended) A pharmaceutical composition in accordance with claim 122, wherein said epitope comprises EFRH (SEQ ID NO: 1).

Claim 145 (Previously Presented) A method in accordance with claim 132, wherein said polypeptide is A β .

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Claim 146 (Previously Presented) A method in accordance with claim 132, wherein said epitope is EFRH (SEQ ID NO: 1), DAEFRH (residues 1-6 of SEQ ID NO: 3), DAEFRHD (residues 1-7 of SEQ ID NO: 3), or DAEFRHDSG (residues 1-9 of SEQ ID NO: 3).

Claim 147 (Previously Presented) A method in accordance with claim 132, wherein said epitope comprises EFRH (SEQ ID NO: 1).

10. Authorization for this examiner's amendment was given in a telephone interview with Roger Browdy on 12 January 2005.

Summary

11. Claims **122, 124, 126-127, 131-132, 134, and 136-147** are hereby allowed.

12. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

January 11, 2005

Elizabeth C. Kemmer

ELIZABETH KEMMER
PRIMARY EXAMINER